regulations under section 505(j)(5)(B)(iv) of the act. In the meantime, the agency must make exclusivity decisions for ANDA's that are nearing approval. Until such time as the rulemaking process is complete, FDA will regulate directly from the statute and will make decisions on 180-day generic drug exclusivity on a case-by-case basis.

The guidance is intended to provide industry with information on how FDA is applying section 505(j)(5)(B)(iv) of the act in light of the decisions in *Mova* and *Granutec*. The agency will revise this guidance as additional interpretations are made.

The guidance is being implemented immediately without prior public comment because the guidance is needed to explain FDA's application of the statute in light of recent court decisions. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance is a level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on 180-day generic drug exclusivity under the Hatch-Waxman Amendments. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the act.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 7, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–18690 Filed 7–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Grantee Reporting Requirements for the Rural Health Network Development Grant Program (OMB NO. 0915–0218)—Extension.

This is a request for extension of the reporting requirements for the Rural Network Development Grant Program authorized by section 330A of the Public Health Service Act as amended by the Health Centers Consolidation Act of 1996 (Public Law 104–229). The purpose of the program is to assist in the development of vertically integrated networks of health care providers in rural communities. Grantees will be working to change the delivery system in their service areas and will be using the Federal funds to develop network capabilities.

Grantees submit semiannual reports which provide information on progress towards goals and objectives of the network, progress toward developing the governance and organizational arrangements for the network, specific network activities, certain financial data related to the grant budget, and health care services provided by the network.

The information is used to evaluate progress on the grants, to understand barriers to network development in rural areas, to identify grantees in need of technical assistance, and to identify best practices in the development of provider networks in rural communities.

The information is also used to begin to evaluate the impact of networks on access to care.

To minimize the burden on grantees, the reports will are submitted electronically. The estimated burden is as follows:

Type of respondent	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Grantees	40	2	20	1,600

Send comments to: HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 7, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–18692 Filed 7–13–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: June 1998

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of June 1998, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party.